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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	Haefner	Examiner:	Kahelin, M.
Serial No.:	10/801,139	Group Art Unit:	3762
Filing Date:	March 15, 2004	Docket No.:	GUID.609PA (03-527)
Title:	IMPLANTABLE DEVICE WITH CARDIAC EVENT AUDIO PLAYBACK		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Appeal Brief - Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, on September 27, 2007.

By: Mark A. Hollingsworth

REPLY BRIEF

Mail Stop Appeal Brief - Patents
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This **Reply Brief** is submitted pursuant to 37 C.F.R. § 41.41 in response to the Examiner's Answer mailed July 27, 2007. This Reply Brief is submitted within two (2) months of the mailing date of the Examiner's Answer, and therefore is timely submitted.

This Reply Brief replicates the Amended Appeal Brief filed on February 19, 2007, with the only exceptions being this cover page and the Argument section (Section VII), which addresses the comments provided in the "Grounds of Rejection" and "Response to Argument" sections of the Examiner's Answer.

While it is believed that no fees are required for submitting this Reply Brief, authority is hereby given to charge deposit account 50-3581 (GUID.609PA) any fees required to effect or otherwise support this filing.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardiac Pacemakers, Inc.

II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals, interferences or judicial proceedings that would have a bearing on the Board's decision in the instant appeal.

III. STATUS OF CLAIMS

Claims 1-48 are pending, each of which is presented for appeal. Each of the pending Claims 1-48 has been finally rejected by the Examiner's action dated February 17, 2006, from which Appellant appeals.

The pending Claims 1-48 under appeal may be found in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the final rejection dated February 17, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is generally directed to cardiac monitoring and/or stimulation methods and systems that, in general, provide for acquisition of audio and electrical signals associated with cardiac activity, such as during cardiac monitoring and/or therapy delivery. Embodiments of the present invention are directed to methods and systems that involve acquisition of audio and electrical signals associated with cardiac activity by a patient-implantable device, and telemetering the audio and electrical signals from the patient-implantable device to a patient-external device. The patient-external device preferably includes a user interface configured for providing a visual output representative of the cardiac electrical signal and an audio output representative of the audio signal.

One embodiment of the present invention is directed to an implantable device. *See, e.g.*, Claim 1, Figs. 1A-C, and the corresponding discussion in the instant Specification at page 13, line 3 – page 20, line 20. The device includes an implantable housing (*e.g.*, 102) and a plurality of implantable electrodes (*e.g.*, 214 and 207) coupled to the housing and configured for sensing cardiac electrical activity. Detection circuitry (*e.g.*, 202) is provided in the housing and coupled to at least some of the plurality of electrodes, the detection circuitry producing a cardiac electrical signal in response to the sensed cardiac electrical activity. An implantable sensor (*e.g.*, 261) is configured to sense movement of a heart and produce a sensor signal in response to the sensed heart movement. Sensor circuitry (*e.g.*, 204) is provided in the housing and coupled to the sensor, the sensor circuitry configured to produce an audio signal in response to the sensor signal. Memory (*e.g.*, 209) is provided in the housing and coupled to the detection circuitry and sensor circuitry, the memory configured to store the audio signal and the cardiac electrical signal. A controller (*e.g.*, 205) is also provided in the housing and coupled to the memory, detection circuitry, and sensor circuitry. Communications circuitry (*e.g.*, 218) is provided in the housing and coupled to the controller, the communications circuitry configured to telemeter the cardiac electrical signal and the audio signal to a patient-external device.

Other embodiments may be directed to a medical system that includes the above-discussed implantable device and a patient-external device. *See, e.g.*, Claim 17, Fig. 1E and the corresponding discussion in the instant Specification at page 22, line 23 – page 27, line 10. The patient-external device (*e.g.*, 420) includes patient-external communications circuitry configured to receive the cardiac electrical signal and the audio signal telemetered from the

patient-implantable device and a user interface coupled to the patient-external communications circuitry configured for providing a visual output representative of the cardiac electrical signal and an audio output representative of the audio signal (*e.g.*, page 24, line 22 – page 25, line2; page 30, lines 20-26).

Another embodiment of the present invention is directed to a method for cardiac monitoring. *See, e.g.*, Claim 32, Fig. 2, and the corresponding discussion in the instant Specification at page 27, line 11 – page 29, line 2. The method includes sensing, from within a patient, movement of a heart and producing a sensor signal in response to the sensed heart movement. An audio signal is produced, within the patient, using the sensor signal. Cardiac electrical activity is detected and a cardiac electrical signal is produced in response to the detected cardiac electrical activity, within the patient. The audio signal and the cardiac electrical signal are stored within the patient and the audio signal and the cardiac electrical signal are telemetered to a patient-external location.

Another embodiment of the present invention is directed to an implantable device. *See, e.g.*, Claim 44, Figs. 1A-C, and the corresponding discussion in the instant Specification at page 13, line 3 – page 20, line 20. The device includes means for detecting a cardiac signal and means for detecting cardiac non-electrophysiologic activity transduceable to an audio signal. The device also includes means for storing the cardiac electrical signal and the audio signal within a patient (*e.g.*, memory 209) and means for communicating the cardiac electrical signal and the audio signal to a patient-external location. The means for detecting a cardiac signal may include, for example: subcutaneous electrodes, *e.g.*, 214; can or indifferent electrodes, *e.g.*, 207; electrode subsystems, *e.g.*, 504, that may include coil electrodes, tip electrodes, ring electrodes, multi-element coils, spiral coils, spiral coils mounted on non-conductive backing, screen patch electrodes, and other electrode configurations; electrode arrays; processing circuitry 316; sensors, *e.g.*, 441, 442, 445, 446; and ECG electrodes used in connection with detection circuitry, *e.g.*, 202, 302; sensing circuitry, *e.g.*, 204, and a control system, *e.g.*, 205. The means for detecting cardiac non-electrophysiologic activity may include, for example: subcutaneous, cutaneous and/or external sensors; a sensor configured to sense pressure waves produced by heart movement; a piezoelectric transducer; a microphone situated in or on the housing, or in or on a lead; blood oxygen sensors; blood volume sensors; acoustic sensors and/or pressure transducers including, *e.g.*, diaphragm based acoustic sensors, MEMS-based

acoustic sensors such as a MEMS-based acoustic transducer, fiber optic acoustic sensors, piezoelectric sensors, and accelerometer-based acoustic sensors and arrays; accelerometers; processing circuitry, *e.g.*, 318; audio sensor, *e.g.*, 502; and phonocardiogram transducers used in connection with detection circuitry, *e.g.*, 202, 302; sensing circuitry, *e.g.*, 204, and a control system, *e.g.*, 205. The means for communicating the cardiac electrical signal and the audio signal include, for example: communications circuitry, *e.g.*, 218; short-range wireless communication interfaces such as Bluetooth and IEEE 802 communication interfaces; proprietary wireless protocols; an APM system, *e.g.*, 440; wire loop antennas; radio frequency telemetric links).

The above embodiment may also include means for playing back the cardiac electrical signal and the audio signal, means for concurrently displaying a representation of the cardiac electrical signal and broadcasting the audio signal, means for concurrently displaying a representation of the detected cardiac electrical signal and broadcasting the detected audio signal in real-time, and means for providing server access to the cardiac electrical signal and the audio signal. *See, e.g.*, Claims 45-48, Fig. 1E, and the corresponding discussion in the instant Specification at page 22, line 23 – page 27, line 10. The means for playing back the signals include, for example: an advanced patient management medical system (*e.g.*, 440), medical device programmers (*e.g.*, 460, 470), patient external device (*e.g.*, 420), audio output devices, speakers, visual displays such as a monitor or other signal display device, patient input/trigger devices, memory, computers (remote or local), and terminals (*e.g.*, 450). The means for concurrently displaying a representation of the detected cardiac electrical signal and broadcasting the detected audio in real-time or otherwise include, for example: an advanced patient management medical system (*e.g.*, 440), medical device programmers (*e.g.*, 460, 470), patient external device (*e.g.*, 420), telecommunications and information technologies, time correlation devices, audio output devices, speakers, visual displays such as a monitor or other signal display device, patient input/trigger devices, memory, computers (remote or local), and terminals (*e.g.*, 450). The means for providing server access include, for example, an advanced patient management medical system (*e.g.*, 440), medical device programmers (*e.g.*, 460, 470), patient information server (*e.g.*, 430), at least one database, and a network. Appellant also notes that a single structure may correspond to multiple "means" limitations. *See, e.g.*,

Winbond Electronics Corp. v. International Trade Commission, 4 Fed.Appx. 832, C.A.Fed., 2001.

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-3, 5-7, 9, 10, 12, 13, 16, 25, 30, 32, 35, 37-39 and 44 stand rejected under 35 U.S.C. §102(b) over Schaldach (U.S. Patent No. 4,867,163).

B. Claims 17, 19-21, 41, 45 and 46 stand rejected under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a) over Schaldach.

C. Claims 4 and 36 stand rejected under 35 U.S.C. § 103(a) over Schaldach in view of Turcott (U.S. Patent No. 6,477,406).

D. Claims 8, 11 and 40 stand rejected under 35 U.S.C. § 103(a) over Schaldach in view of Kadhiresan (U.S. Patent No. 5,935,081).

E. Claims 14, 18, 22-24, 31, 33, 34, 43 and 47 stand rejected under 35 U.S.C. § 103(a) over Schaldach in view of Gessman (U.S. Patent No. 5,321,618).

F. Claims 15, 26-29, 42 and 48 stand rejected under 35 U.S.C. § 103(a) over Schaldach in view of Riff *et al.* (U.S. Publication No. 2002/0026223).

VII. ARGUMENT

Beginning on page 3 and ending on page 9 of the Examiner's Answer ("Grounds of Rejection"), a detailed claim chart is presented in which limitations of Appellant's claims are charted against selected portions of Schaldach that purportedly disclose such limitations. Appellant notes that this chart had not been previously presented in any of the Examiner's prior communications, but appears for the first time in the Examiner's Answer.

Appellant does not acquiesce to the accuracy of the content of the Examiner's claim chart or the correspondence between claim limitations and the selected portions of Schaldach, although inaccuracies have been noted by Appellant. For example, element 116 identified on pages 4, 5, and 6 of the chart is cited as corresponding to Appellant's "communications circuitry" recited in independent Claims 1, 17, and 32. Element 116 is not described as communications circuitry in Schaldach nor circuitry configured to telemeter signals to a patient-external device, but is instead described as an input/output unit. The chart also omits correspondence information for Appellant's independent Claim 44. In the interest of brevity, Appellant believes it unnecessary to address the detailed correspondence chart presented in the Examiner's Answer, other than the content's bearing on the issues on appeal, primarily in regard to independent Claims 1, 17, 32, and 44.

Each of independent Claims 1, 17, 32 and 44 includes limitations directed to communicating both a cardiac electrical signal and an audio signal representative of a cardiac non-electrophysiologic activity (*e.g.*, heart movement) to a patient-external location or device. In particular, Claims 1 and 17 recite sensor circuitry configured to produce an audio signal in response to a sensor signal produced by an implantable sensor configured to sense heart movement. Claims 32 and 44 recite producing, within a patient, an audio signal using a sensor signal produced from implantably sensing heart movement.

Appellant maintains that Schaldach does not teach sensor circuitry configured to produce an audio signal in response to the sensor signal as recited in Claims 1 and 17, and also does not teach producing, within a patient, an audio signal using a sensor signal produced within the patient as recited in Claims 32 and 44. Appellant further maintains that Schaldach does not teach communication of both a cardiac electrical signal and an audio signal representative of a cardiac non-electrophysiologic activity to a patient-external location.

On page 9 of the Examiner's Answer, the Examiner maintains that Schaldach's disclosure of displaying various data using an external display in visual form corresponds to Appellant's claim recitations of communicating both a cardiac electrical signal and an audio signal to a patient-external location or device. The Examiner states that the pressure or sound pickup signals, as described at col. 7, line 60, that are presented to a user in visual form are, nonetheless, "audio signals" that are communicated to a patient-external device.

On page 10 of the Examiner's Answer, the Examiner states that the modifier "audio" does not require that the signal be capable of being heard by an ear, and that "audio output" does not require that the output be capable of being heard by a human ear any more than the "audio signal," which is transferred over wires and an RF telemetry interface, be capable of being heard by a human ear.

During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369 (Fed. Cir. 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation in light of the specification.). According to MPEP §2111.01, this means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the Specification.

Claims must be given their broadest reasonable interpretation consistent with the Specification, as it would be interpreted by one of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)(citing *In re American Academy of Science Tech Center, Id.*). Appellant respectfully submits that the Examiner's interpretation of the term "audio signal" recited in Appellant's claims is not a reasonable interpretation in light of how this term would be interpreted by one of ordinary skill in the art and is not consistent with Appellant's Specification.

Appellant's Specification describes what is meant by the term "audio signal" in a manner that is consistent with how this term would be interpreted by one of ordinary skill in the art. Appellant's Specification teaches, for example, that:

> Various types of acoustic sensors may be used to detect heart sounds and utilized as the audio sensor 502. Examples of such acoustic sensors include diaphragm based acoustic sensors, MEMS-based acoustic sensors such as a MEMS-based acoustic transducer, fiber optic acoustic sensors, piezoelectric sensors, and accelerometer based acoustic sensors and arrays. These sensors may be used to detect the audio frequency pressure waves associated with the heart sounds, and may also be used to detect other non-electrophysiological cardiac related signals. Page 28, line 21-page 29, line 2 (*emphasis added*).

> The opening and closing of the patient's heart valves during a heartbeat causes high-frequency vibrations in the adjacent heart wall and blood vessels. These vibrations may be *heard* in the patient's body as heart sounds, and may be detected by sensors, as described earlier. A conventional phonocardiogram (PCG) transducer placed on a patient converts the acoustical energy of the heart sounds to electrical energy, resulting in a PCG waveform 820 that may be recorded and displayed, as shown by the graph in the upper middle portion of Figure 3. Page 29, lines 14-20 (*emphasis added*).

> As indicated by the PCG waveform 820 shown in Figure 3, a typical heartbeat produces two main heart sounds. A first heart sound 830, denoted S1, is generated by vibration generally associated with the closure of the tricuspid and mitral valves at the beginning of systole. Typically, the heart sound 830 is about 14 milliseconds long and contains frequencies up to approximately 500 Hz. A second heart sound 840, denoted S2, is generally associated with vibrations resulting from the closure of the aortic and pulmonary valves at the end of systole. While the duration of the second heart sound 840 is typically shorter than the first heart sound 830, the spectral bandwidth of the second heart sound 840 is typically larger than that of the first heart sound 830. Page 29, line 21-page 30, line 3 (*emphasis added*).

Appellant's Specification makes clear that the term "audio signal" refers to a signal that contains "audio frequency" signal information (e.g., "audio frequency pressure waves associated with the heart sounds"; "vibrations [that] may be *heard* in the patient's body as heart sounds, and may be detected by sensors," as cited above).

The audio frequency range is well understood by those of ordinary skill in the art as a frequency range corresponding to that of human hearing. "It is well known that audio frequencies range from approximately 20 Hz to approximately 20 kHz." U.S. Patent Application Publication Nos. 2007/0098182 and 2007/0030983 at paragraph [0002]. *See also,* U.S. Patent Nos. 6,917,911 ("The audio-frequency range of human hearing is about 20 Hz to 20,000 Hz."); 6,822,929 (". . . the audio-frequency range (100 Hz to 20 kHz) . . .".).

Appellant respectfully submits that the Examiner's interpretation of the term "audio signal" effectively and impermissibly reads out of this claim term the word (i.e., limitation) "audio." The Examiner's interpretation effectively ignores or reads out of Appellant's Claims 1 and 17 sensor circuitry configured to produce an audio signal in response to a sensor signal produced by an implantable sensor configured to sense heart movement. Further, the Examiner's interpretation effectively ignores or reads out of Appellant's Claims 32 and 44 producing, within a patient, an audio signal using a sensor signal produced within the patient in response to heart movement.

On page 10 of the Examiner's Answer, the Examiner maintains that "audio output" does not require that the output be capable of being heard by a human ear. The instant claims and Specification clearly discern, in accordance with the common understanding of the terms "visual" and "audio," that the terms refer to discrete output modes. For example, Claim 17 recites a "user interface configured for providing a *visual output* representative of the cardiac electrical signal and an *audio output* representative of the audio signal." Appellant maintains that a visual output is an output that can be seen and an audio output is an output that can be heard. Further, Claim 18, which is dependent on Claim 17, differentiates the above audio output by reciting "the user interface is configured for providing a visual output representative of the audio signal." Thus, by claim differentiation, the audio output of the audio signal recited in Claim 17 is different from the visual output of the audio signal recited in claim 18. Schaldach does not teach or suggest a user interface that provides an audio output as recited in Claim 17, and no demonstrable evidence has been presented to show otherwise.

Schaldach does not use the term "audio" anywhere in its disclosure. The term "acoustic" is used once by Schaldach to describe a type of receiver that detects the presphygmic period and systolic discharge time. There is no indication that these timing variables are detected as audio signals nor that they are communicated to a patient-external device. Moreover, Schaldach describes control unit 150 (the asserted patient-external device) as having only a graphical display – there is no indication that the control unit 150 receives an audio signal or provides an audio output.

On page 9 of the Examiner's Answer, the Examiner asserts that Schaldach discloses manipulating various combinations of sensed variables with an external display, and makes

reference to column 23, lines 20-65 and column 26, line 18-column 27, line 29. The Examiner further asserts that an example of such sensed variables is use of the "pressure or sound pickups" of column 7, line 60, and that Schaldach's displaying of PEP in Figure 6e is a variable determined with a mechanical/audio sensor, which corresponds to Appellant's claimed "audio signal" that is communicated to a patient-external device.

Figure 6e of Schaldach is reproduced below:

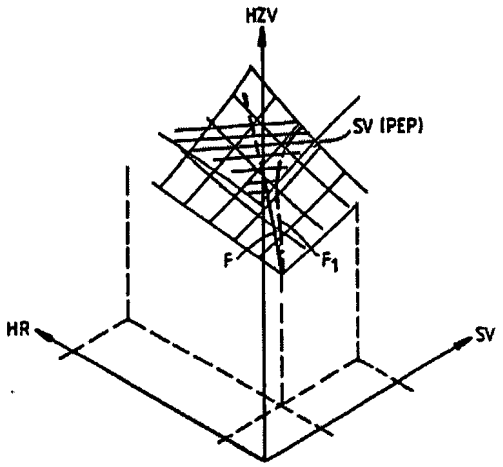

Fig.6e

The visual displays of Figure 6e and Figures 6a-d discussed in column 23 are graphical depictions of combinations of input variables and/or parameters. The sound pickups are "pressure or sound pickups" that have a relationship to measured values having a relationship to mechanical contractions, and are converted and digitally processed. *See, e.g.*, column 8, lines 5-18. As is clearly taught in Schaldach, the pressure or sound pickups "can advantageously be utilized for varying the pacing parameters (in particular, heart rate)." Column 7, lines 53-68 (*emphasis added*).

There is no teaching in Schaldach that supports the Examiner's assertion that the visual display of PEP in Figure 6e, for example, can somehow be construed as an "audio signal" of the type contemplated in Appellant's claims, irrespective of whether the PEP graph is displayed or aurally broadcast, assuming such is even possible. This assertion is mere supposition that is not supported by the Schaldach disclosure.

Appellant's careful review of Schaldach reveals no teaching or suggestion in Schaldach that any audio signal or other signal containing audio signal information is telemetered to a patient-external device along with a cardiac electrical signal. The reason for this absence of teaching appears clear, given the use of the signals derived from the measured value pickups (e.g., 117-120 in Figure 1) in Schaldach. As was strenuously argued in Appellant's prior responsive communications, the signals derived from the measured value pickups, such as the "pressure or sound pickups" of column 7, line 60, are used to control pacing, including pacing rate. In particular, Schaldach, at column 20, lines 67-68, describes that the pressure or sound pickups measure stroke volume which is used in controlling pacing, including pacing rate.

Any audio signals derived from the measured value pickups 117-120 are used to control pacing, and are not described as being of interest beyond the context of pacing control. There is simply no teaching or suggestion by Schaldach that an audio signal is communicated outside the body by the disclosed device. Schaldach only teaches that a microphone may be used to derive measured values such as stroke volume, but does not teach that an audio signal of the type contemplated in Appellant's claims is produced from the microphone, or that any such audio signal is stored and/or communicated to a patient-external device.

Respectfully, the rejection of independent Claims 1, 17, 32, and 44 under 35 U.S.C. §102(b) is not sustainable, as the Examiner has not established *prima facie* anticipation of each and every element recited in these claims. The disclosure in an anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). See, also, MPEP § 2121.01.

Appellant respectfully asserts that Schaldach's description of a rate-adaptive pacemaker that uses sound pickups to derive measured value pickup signals for the stated purpose of controlling pacing or pacing rate is insufficient to support the Examiner's anticipation rejection of Appellant's Claims 1, 17, 32, and 44. There is no indication as to how one skilled in the art could arrive at Appellant's claimed structure and functionality using Schaldach's rate-adaptive pacemaker teachings without undue experimentation, particularly in the clear absence of a

teaching regarding telemetering of an audio signal or other signal containing audio signal information to a patient-external device along with a cardiac electrical signal.

Dependent Claims 2, 3, 5-7, 9, 10, 12, 13, 16, 17, 19-21, 25, 30, 35, 37-39, 41, 45 and 46 depend from independent Claims 1, 17, 32 and 44, respectively, and also stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schaldach. While Appellant does not acquiesce with the particular rejections to these dependent claims, these rejections are also improper for the reasons discussed above in connection with independent Claims 1, 17, 32, and 44. These dependent claims include all of the limitations of their respective base claims and any intervening claims and recite additional features which further distinguish these claims from the cited reference. Therefore, the rejection of dependent Claims 2, 3, 5-7, 9, 10, 12, 13, 16, 35 and 37-39 is improper.

Concerning the various rejections of dependent claims under 35 U.S.C. §103(a) summarized above, each of these dependent claims depends from independent Claim 1, 17, 32, or 44. For the reasons set forth above, independent Claims 1, 17, 32, and 44 are not anticipated or rendered obvious in view of *Schaldach*. For example, and as discussed above, the asserted references fail to teach or suggest all limitations of Appellant's independent claims. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." M.P.E.P. §2143.03; *citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

VIII. CONCLUSION

In view of the above, Appellant respectfully submits that the claimed invention is patentable over the cited references and that the rejections of Claims 1-48 should be reversed. Appellant respectfully requests reversal of the rejections as applied to the appealed claims and allowance of the entire application.

Authorization to charge the undersigned's deposit account is provided on the cover page of this brief.

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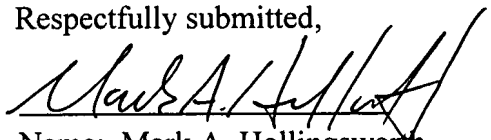
Respectfully submitted,



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CLAIMS APPENDIX

1. An implantable device, comprising:

an implantable housing;

a plurality of implantable electrodes coupled to the housing and configured for sensing cardiac electrical activity;

detection circuitry provided in the housing and coupled to at least some of the plurality of electrodes, the detection circuitry producing a cardiac electrical signal in response to the sensed cardiac electrical activity;

an implantable sensor configured to sense movement of a heart and produce a sensor signal in response to the sensed heart movement;

sensor circuitry provided in the housing and coupled to the sensor, the sensor circuitry configured to produce an audio signal in response to the sensor signal;

memory provided in the housing and coupled to the detection circuitry and sensor circuitry, the memory configured to store the audio signal and the cardiac electrical signal;

a controller provided in the housing and coupled to the memory, detection circuitry, and sensor circuitry; and

communications circuitry provided in the housing and coupled to the controller, the communications circuitry configured to telemeter the cardiac electrical signal and the audio signal to a patient-external device.

2. The device of claim 1, wherein the sensor comprises an accelerometer.

3. The device of claim 1, wherein the sensor is configured to sense pressure waves produced by the heart movement.

4. The device of claim 1, wherein the sensor comprises a piezoelectric transducer.

5. The device of claim 1, wherein the sensor comprises a microphone.

6. The device of claim 1, wherein the sensor is situated in or on the housing.

7. The device of claim 1, further comprising a lead wherein the sensor is provided in or on the lead.

8. The device of claim 1, wherein at least one of the plurality of electrodes is configured for subcutaneous, non-intrathoracic placement.

9. The device of claim 1, wherein at least one of the plurality of electrodes is configured for intrathoracic placement.

10. The device of claim 1, wherein at least one of the plurality of electrodes is disposed in or on the housing.

11. The device of claim 1, further comprising a lead wherein at least one of the plurality of electrodes is supported by the lead configured for subcutaneous, non-intrathoracic placement, the lead coupling the at least one of the plurality of electrodes to the housing.

12. The device of claim 1, further comprising energy delivery circuitry coupled to the controller and at least some of the plurality of electrodes, the energy delivery circuitry configured to deliver a cardiac therapy.

13. The device of claim 12, wherein the cardiac therapy comprises a cardiac pacing therapy.

14. The device of claim 12, wherein the cardiac therapy comprises a cardiac defibrillation therapy.

15. The device of claim 1, further comprising a patient actuatable trigger configured to communicate a trigger signal to the controller via the communications circuitry, the controller initiating storing of the cardiac electrical signal and the audio signal in the memory in response to the trigger signal.

16. The device of claim 1, wherein at least one of the cardiac electrical signal and the audio signal are telemetered from the patient-implantable device in response to a trigger signal.

17. A medical system, comprising:

a patient-implantable device, comprising:

a housing;

a plurality of electrodes coupled to the housing and configured for sensing cardiac electrical activity;

detection circuitry provided in the housing and coupled to at least some of the plurality of electrodes, the detection circuitry producing a cardiac electrical signal in response to the sensed cardiac electrical activity;

a sensor configured to sense movement of a heart and produce a sensor signal in response to the sensed heart movement;

sensor circuitry provided in the housing and coupled to the sensor, the sensor circuitry configured to produce an audio signal in response to the sensor signal;

memory provided in the housing and coupled to the detection circuitry and sensor circuitry, the memory configured to store the audio signal and the cardiac electrical signal;

a controller provided in the housing and coupled to the memory, detection circuitry, and sensor circuitry; and

communications circuitry provided in the housing and coupled to the controller, the communications circuitry configured to telemeter the cardiac electrical signal and the audio signal; and

a patient-external device comprising:

patient-external communications circuitry configured to receive the cardiac electrical signal and the audio signal telemetered from the patient-implantable device; and

a user interface coupled to the patient-external communications circuitry, the user interface configured for providing a visual output representative of the cardiac electrical signal and an audio output representative of the audio signal.

18. The system of claim 17, wherein the user interface is configured for providing a visual output representative of the audio signal and an audio output representative of the cardiac electrical signal.

19. The system of claim 17, wherein the user interface comprises a display configured to display a representation of one or both of the cardiac electrical signal and the audio signal.

20. The system of claim 17, wherein the user interface comprises a display configured to display one or both of textual and graphical information associated with one or both of the cardiac electrical signal and the audio signal.

21. The system of claim 17, wherein the user interface comprises an audio output device configured to broadcast the audio signal.

22. The system of claim 17, wherein the communications_circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in response to a user request.

23. The system of claim 17, wherein the communications_circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in response to a request by the patient-external device.

24. The system of claim 17, wherein the communications_circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in real-time.

25. The system of claim 17, wherein the patient-external device further comprises a storage media to store the cardiac electrical signal and the audio signal telemetered from the patient-implantable device.

26. The system of claim 17, further comprising a server communicatively coupled to one of the patient-implantable device and the patient-external device.

27. The system of claim 17, further comprising a server communicatively coupled to the patient-implantable device and the patient-external device.

28. The system of claim 17, further comprising a server communicatively coupled to the patient-implantable device and the patient-external device, wherein the cardiac electrical signal and the audio signal are telemetered from the patient-implantable device to the server and communicated from the server to the patient-external device.

29. The system of claim 17, further comprising a server communicatively coupled to the patient-external device, wherein the cardiac electrical signal and the audio signal are telemetered from the patient-implantable device to the patient-external device and communicated from the patient-external device to the server.

30. The system of claim 17, wherein at least one of the patient-implantable device and patient-external device provides a time correlation between the cardiac electrical signal and the audio signal.

31. The system of claim 30, wherein the user interface comprises:

a speaker configured to broadcast the audio signal; and

a display configured to display a representation of the cardiac electrical signal and indicia indicative of the time correlation.

32. A method, comprising:

sensing, from within a patient, movement of a heart and producing a sensor signal in response to the sensed heart movement;

producing, within the patient, an audio signal using the sensor signal;

detecting, within the patient, cardiac electrical activity and producing a cardiac electrical signal in response to the detected cardiac electrical activity;

storing, within the patient, the audio signal and the cardiac electrical signal; and

telemetering the audio signal and cardiac electrical signal to a patient-external location.

33. The method of claim 32, wherein the audio signal and cardiac electrical signal are telemetered to the patient-external location in response to a trigger signal generated by a patient-actuated device.

34. The method of claim 32, wherein the audio signal and cardiac electrical signal are telemetered to a patient-external system in response to a trigger signal generated by the patient-external system.

35. The method of claim 32, wherein the sensor signal comprises an accelerometer signal.

36. The method of claim 32, wherein the sensor signal comprises a piezoelectric transducer signal.

37. The method of claim 32, wherein the sensor signal comprises a microphone output signal.

38. The method of claim 32, wherein storing comprises time correlating the audio signal and the cardiac electrical signal.

39. The method of claim 32, wherein detecting comprises detecting the cardiac electrical activity intrathoracically.

40. The method of claim 32, wherein detecting comprises detecting the cardiac electrical activity from one or more subcutaneous, non-intrathoracic locations.

41. The method of claim 32, further comprising broadcasting the audio signal and displaying a representation of the cardiac electrical signal.

42. The method of claim 32, further comprising communicating the audio signal and the cardiac electrical signal to a server system.

43. The method of claim 32, further comprising telemetering the detected sensor signal and cardiac electrical signal in real-time.

44. An implantable device, comprising:

means for detecting a cardiac electrical signal;

means for detecting cardiac non-electrophysiologic activity transduceable to an audio signal;

means for storing the cardiac electrical signal and the audio signal within a patient; and

means for communicating the cardiac electrical signal and the audio signal to a patient-external location.

45. The device of claim 44, further comprising means for playing back the cardiac electrical signal and the audio signal.

46. The device of claim 44, further comprising means for concurrently displaying a representation of the cardiac electrical signal and broadcasting the audio signal.

47. The device of claim 44, further comprising means for concurrently displaying a representation of the detected cardiac electrical signal and broadcasting the detected audio signal in real-time.

48. The device of claim 44, further comprising means for providing server access to the cardiac electrical signal and the audio signal.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.